International Application No.: PCT /US2004/032714

International Filing Date: October 4, 2004

PRELIMINARY AMENDMENT

Express Mail Label No.: EV 487329986 US

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In the claims

Please amend the claims as follows:

1. (currently amended) A topical foam aerosol formulation comprising

(a) an active agent or agents selected from the group consisting of anti-inflammatory

agents, topical anesthetics, topical antibiotics, anti-fungal agents, and combinations thereof,

solubilized or dispersed in an oil and water emulsion in the absence of, wherein the emulsion

does not contain volatile lower alcohols; and

(b) a hydrofluoroalkane propellant consisting essentially of a hydrofluoroalkane or a

mixture of hydrofluoroalkanes, without additional co-solvents or co-propellants, contacting

the emulsion to produce an immediate foaming action on expulsion from a pressurized

container.

2. (currently amended) The formulation of clam 1 wherein the active agent is

selected from the group consisting of anti-inflammatory agents; topical anesthetics; topical

antibiotics, anti-fungal agents; sunscreens and combinations thereof comprising a water-

insoluble active agent in the oil phase and a water-soluble active agent in the aqueous phase.

3. (original) The formulation of claim 2 wherein the active agent is an anti-

inflammatory agent.

4. (original) The formulation of claim 3 wherein the anti-inflammatory agent is

selected from the group consisting of alclometasone dipropionate, amcinonide,

beclamethasone dipropionate, betamethasone benzoate, betamethasone dipropionate,

betamethasone valerate, budesonide, clobetasol propionate, clobetasone butyrate, desonide,

desoxymethasone, diflorasone diacetate, diflucortolone valerate, flumethasone pivalate,

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fluclorolone acetonide, fluocinolone acetonide, fluocionoide, fluocortin butyl, flucortolones,

fluprednidene acetate, flurandrenolone, halcinonide, hydrocortisone, hydrocortisone acetate,

hydrocortisone butyrate, methylprednisolone acetate, nometasone furoate, triamcinolone

acetonide, diclofenac, ibuprofen, acetylsalicylic acid, piroxicam, ketoprofen, felbinac,

benzylamine, and combinations thereof.

5. (original) The formulation of claim 3 wherein the concentration of the anti-

inflammatory agent is from about 0.01% to 10%.

6. (original) The formulation of claim 2 wherein the active agent is a topical

anesthetic.

7. (original) The formulation of claim 6 wherein the topical anesthetic is selected

from the group consisting of lidocaine, prilocaine, bupivacaine, levo-bupivacaine,

ropivacaine, mepivacaine, procaine, chloroprocaine, propoxycaine, hexylcaine, tetracaine,

cyclomethycaine, benoxinate, butacaine, proparacaine, butamben, diperodon, phenacaine,

falicaine, dyclonine, pramoxine, dimethisoquien, benzocaine, amethocaine, dibucaine,

ketocaine, propanocaine, propipocaine, and combinations thereof.

8. (original) The formulation of claim 6 wherein the concentration of the anesthetic

is from about 1% to about 10%.

9. (original) The formulation of claim 2 wherein the active agent is an antibiotic or

antifungal agent.

10. (currently amended) The formulation of claim 9 wherein the active agent is an

antifungal agent is selected from the group consisting of clotrimazole, econazole,

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ketoconazole, itraconazole, miconazole, oxiconazole, sulconazole, butenafine, naftifine,

terbinafine, undecylinic acid, tolnaftate, and nystatin, and sertaconazole nitrate.

11. (original) The formulation of claim 9 wherein the concentration of the antifungal

or antibiotic agent is from about 0.3% to 5%.

12. (currently amended) A method of making a HFA hydrofluoroalkane containing

topical foam formulation free of volatile lower alcohols comprising

(a) making an oil in water emulsion with a predominantly, more than 50%, aqueous

phase,

(b) either dissolving drug or drugs an active agent or agents selected from the group

consisting of anti-inflammatory agents, topical anesthetics, topical antibiotics, anti-fungal

agents, and combinations thereof in the aqueous or oil phase prior to emulsification or adding

non-water soluble, non-oil soluble drug to the emulsion to form a dispersion in the emulsion,

and

(c) adding an HFA a propellant consisting essentially of a hydrofluoroalkane or a

mixture of hydrofluoroalkanes, without additional co-solvents or co-propellants, to the

emulsion to produce an immediate foaming action on expulsion from a pressurized container.

13. (currently amended) A HFA hydrofluoroalkane containing topical foam

formulation free of volatile alcohols produced by the method of claim 12.

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